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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.        |
|--|-------------|----------------------|---------------------|-------------------------|
| 10/594,439   | 07/23/2007  | Hector Velez-Rivera  | VELEZ-RIVERA 1      | 6855                    |
| 1444   | 7590        | 12/03/2008           | EXAMINER            |                         |
| BROWDY AND NEIMARK, P.L.L.C.<br>624 NINTH STREET, NW<br>SUITE 300<br>WASHINGTON, DC 20001-5303 |             |                      |                     | TATE, CHRISTOPHER ROBIN |
| ART UNIT   |             | PAPER NUMBER         |                     |                         |
| 1655   |             |                      |                     |                         |
| MAIL DATE  |             | DELIVERY MODE        |                     |                         |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                      |  |
|------------------------------|------------------------|----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>  |  |
|                              | 10/594,439             | VELEZ-RIVERA, HECTOR |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>      |  |
|                              | Christopher R. Tate    | 1655                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 4-12 is/are rejected.
- 7) Claim(s) 2 and 3 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____ .                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0906</u> .  | 6) <input type="checkbox"/> Other: ____ .                         |

## **DETAILED ACTION**

Claims 1-12 are presented for examination on the merits.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is rendered vague and indefinite by the phrase "vegetable extracts such as *Curcuma longa*; ... in combination with oil of *Oenothera biennis*" (lines 1-3). It is unclear by this overall phrase if all of the recited herbals are necessarily included therein - e.g., the terminology "such as" within this phrase makes it unclear as to which and how many of the recited herbals are actually contained therein.

Claims 10-12 provide for the use of the recited herbal ingredients, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Please note that, as drafted, claims 10-12 have been interpreted as product claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 6, 7, and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (US 6,210,738) or over McClung (US 6,579,543).

A composition comprising extracts of *Curcuma longa* (aka turmeric), *Harpagophytum procumbens* (aka devil's claw), *Filipendula ulmaria* (aka meadowsweet or meadow sweet), and *Oenothera biennis* oil (aka evening primrose oil) is claimed.

Each of the cited references beneficially teach a composition which comprises, or may comprise, *Curcuma longa* (turmeric), *Harpagophytum procumbens* (devil's claw root), *Filipendula ulmaria* (meadowsweet), and *Oenothera biennis* oil (evening primrose oil) as bioactive ingredients therein, including in combination within one or more pharmaceutically acceptable vehicles/carriers. That is, Chen teaches that these herbals each act as natural health promoting ingredients within an oral tea formulation (see, e.g., col 6, line 49 - col 7, line 47, and claims 1 and 6) - please note that a tea formulation would intrinsically provide the recited herbals in the form of an extract thereof (since such a tea is prepared via contacting the herbals with hot water which would intrinsically act as an extraction solvent - including for extracting the naturally occurring oil within the evening primrose plant); and McClung teaches that these herbals (as well as extracts thereof) are effectively useful together for topically treating pain and discomfort caused by a medical condition (such as joint inflammation) or physical injury (see, e.g., col 2, line 39 - col 3, line 8; col 9, line 48 - col 10, line 16; col 11, lines 59-67; col 16, lines 25-35; col 17, lines 16-65; and claims 1 and 7).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose (with respect to the purposes disclosed by each of the cited references, as discussed above) and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. This rejection is based on the well established proposition of patent law that no

invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. In re Kerkhoven, 626 F.2d 846, 850, 205 U.S.P.Q. 1069 (CCPA 1980), In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients (such as the amounts thereof as defined in instant claims 2-3, which are reasonably disclosed/demonstrated by the instant disclosure to provide such a synergistic effect).

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him/her.

From the teachings of each of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by each of the cited references, especially in the absence of evidence to the contrary.

Claims 1 and 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (US 6,210,738) in view of Oppenheim et al. (WO 99/20289).

The teachings of Chen are relied upon for the reasons set forth above. Chen does not expressly teach employing alcoholic or hydroalcoholic extracts of such bioactive herbal ingredients nor incorporating them within a pharmaceutical form such as a gelatin capsule.

Oppenheim et al. beneficially teaches the conventional steps for preparing bioactive herbal extracts such as obtained from *Curcuma longa* (turmeric), *Harpagophytum procumbens* (devil's claw), *Filipendula ulmaria* (meadowsweet) - whereby the bioactive plant material can be effectively extracted using solvents such as alcohols, water, and mixtures thereof. Oppenheim et al. also disclose incorporating such bioactive herbal extracts within a soft gelatin capsule including one which includes evening primrose oil as a suitable fill liquid therein (see entire document including, e.g., pages 2-3, 7, 14, and claim 27).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare aqueous, alcoholic, and/or hydroalcoholic extracts of one or more of the natural health promoting herbal ingredients beneficially taught by Chen (including *Curcuma longa* (turmeric), *Harpagophytum procumbens* (devil's claw), *Filipendula ulmaria* (meadowsweet), as well as to incorporate such natural health promoting extracts within a soft gelatin capsule containing evening primrose oil therein based upon the beneficial teachings provided by Oppenheim et al., as discussed above. The result-effective adjustment of these and other types of conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited references before him/her as a guide.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

With respect to some of the art rejections above, it is noted that the references do not necessarily teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

### ***Claim Objections***

Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655